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September 5, 1997

Ex Parte

Matthew G. Nagler
Network Services Division
Common Carrier Bureau
Federal Communications Commission
2000 M Street, N.W.
Room 235
Washington, D.C. 20554

Re: Ex Parte Submission
CC Docket No. 96-254

Dear Mr. Nagler:

Attached, in response to your recent request, are copies of ISO/IEC Guide Nos. 25, 43, and 58.

Respectfully submitted,

John L. McGrew

Attachments

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GUIDE 25

General requirements for the competence of calibration and testing laboratories

Third edition 1990

Contents

International Organization for Standardization
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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) together form a system for worldwide standardization as a whole. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

This third edition of ISO/IEC Guide 25 was drawn up by the ISO Council Committee on conformity assessment (CASCO), in response to a request arising from ILAC '88, the International Laboratory Accreditation Conference held in Auckland (New Zealand) on 17-21 October 1988.

It was approved by the IEC Council in October 1990 and by the ISO Council in December 1990.

The documents produced by CASCO are issued as Guides and follow the general rules for development and promulgation of ISO and IEC standards except that they are the result of a consensus reached within a Council committee, endorsed by the ISO Council and the IEC Council.

The work of ISO/CASCO in preparing Guides, uses as a basis the principle that third party certification systems should, to the extent possible, be based on internationally agreed standards and procedures. While recognizing the major role of manufacturers' declaration of conformity through normal manufacturer/customer relationship, Council resolutions have emphasized the preparation of guidance documents on third party conformity assessment procedures in order that national systems may be compatible with one another so as to facilitate bilateral and multilateral agreements.

Whilst these documents are intended to provide guidance, it is hoped that any changes from the documents made in introducing systems nationally would be minimal. In recognizing that some countries may choose to adopt the Guides directly, they are written to enable this to be done by including words such as "shall" to indicate those aspects which desirably would be mandatory. The overriding basis that the document is intended to provide guidance holds good.

General requirements for the competence of calibration and testing laboratories

Introduction

Since ISO/IEC Guide 25 was last revised in 1982 the use of quality systems in laboratories has greatly increased. Many countries have adopted ISO/IEC Guide 25 as the basis both for establishing quality systems in laboratories and for recognizing their competence, e.g. by accreditation. In recent years there have been many developments in the field of quality assurance which have led to new and improved guides and standards; it was recognized that there was a need to revise ISO/IEC Guide 25 to reflect these changes.

In this revision of the Guide attention is paid to the activities of both calibration and testing laboratories and account is taken of other requirements for laboratory competence such as those laid down in the OECD *Code of Good Laboratory Practice* (GLP) and the ISO 9000 series of quality assurance standards.

This Guide should provide a mechanism for promoting confidence in calibration and testing laboratories that can show that they operate in accordance with its requirements.

Acceptance of calibration and test results between countries will facilitate the removal of non-tariff barriers to trade.

The use of this Guide will facilitate cooperation between laboratories and other bodies to assist in the exchange of information and experience, and in the harmonization of standards and procedures.

This Guide is specific to calibration laboratories and testing laboratories.

Laboratories meeting the requirements of this Guide comply, for calibration and testing activities, with the relevant requirements of the ISO 9000 series of standards, including those of the model described in ISO 9002 when they are acting as suppliers producing calibration and test results.

For laboratories engaged in specific fields of testing such as the chemical field (see for example the OECD *Code of Good Laboratory Practice*) or the information technology field, the requirements of this Guide will need amplification and interpretation, as referred to in clause 4.2 of ISO/IEC Guide 55.

1 Scope

1.1 This Guide sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific calibrations or tests.

1.2 Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria may be specified by the organization or authority granting the recognition (or approval), depending upon the specific character of the task of the laboratory.

1.3 This Guide is for use by calibration and testing laboratories in the development and implementation of their quality systems. It may also be used by accreditation bodies, certification bodies and others concerned with the competence of laboratories.

2 References

ISO 8402 : 1986, *Quality — Vocabulary.*

ISO 9000 : 1987, *Quality management and quality assurance standards — Guidelines for selection and use.*

ISO 9001 : 1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

ISO 9002 : 1987, *Quality systems — Model for quality assurance in production and installation.*

ISO 9003 : 1987, *Quality systems — Model for quality assurance in final inspection and test.*

ISO 9004 : 1987, *Quality management and quality system elements — Guidelines.*

ISO/IEC Guide 2 : 1986, *General terms and their definitions concerning standardization and related activities.*

International vocabulary of basic and general terms in metrology (VIM) : 1984, issued by BIPM, IEC, ISO and OIML.

3 Definitions

The relevant definitions from ISO/IEC Guide 2, ISO 8402 and the *International vocabulary of basic and general terms in metrology* (VIM) are applicable, the most relevant being quoted below together with further definitions applicable for the purposes of this Guide.

3.1 laboratory: Body that calibrates and/or tests.

NOTES

1 In cases where a laboratory forms part of an organization that carries out other activities besides calibration and testing, the term "laboratory" refers only to those parts of that organization that are involved in the calibration and testing process.

2 As used herein, the term "laboratory" refers to a body that carries out calibration or testing

- at or from a permanent location,
- at or from a temporary facility, or
- in or from a mobile facility.

3.2 testing laboratory: Laboratory that performs tests.

[ISO/IEC Guide 2 — 12.4]

3.3 calibration laboratory: Laboratory that performs calibration.

3.4 calibration: The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurand.

NOTES

1 The result of a calibration permits the estimation of errors of indication of the measuring instrument, measuring system or material measure, or the assignment of values to marks on arbitrary scales.

2 A calibration may also determine other metrological properties.

3 The result of a calibration may be recorded in a document, sometimes called a **calibration certificate** or a **calibration report**.

4 The result of a calibration is sometimes expressed as a **calibration factor**, or as a series of calibration factors in the form of a **calibration curve**.

[VIM — 6.13]

3.5 test: A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

NOTE — The result of a test is normally recorded in a document sometimes called a **test report** or a **test certificate**.

[ISO/IEC Guide 2 — 12.1, amended]

3.6 calibration method: Defined technical procedure for performing a calibration.

3.7 test method: Defined technical procedure for performing a test.

3.8 verification: Confirmation by examination and provision of evidence that specified requirements have been met.

NOTE — In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

The result of verification leads to a decision either to restore to service, or to perform adjustments, or to repair, or to downgrade, or to declare obsolete. In all cases it is required that a written trace of the verification performed be kept on the measuring instrument's individual record.

3.9 quality system: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

[ISO 8402 — 3.8, without the notes]

3.10 quality manual: A document stating the quality policy, quality system and quality practices of an organization.

NOTE — The quality manual may call up other documentation relating to the laboratory's quality arrangements.

3.11 reference standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

[VIM — 6.08]

3.12 reference material: A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

[ISO Guide 30 — 2.1]

3.13 certified reference material (CRM): A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

[ISO Guide 30 — 2.2]

3.14 traceability: The property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

[VIM — 6.12]

[A note given in the VIM to this definition applies to the French text only.]

3.15 proficiency testing: Determination of the laboratory calibration or testing performance by means of interlaboratory comparisons.

[ISO/IEC Guide 2 — 12.6, amended]

3.16 requirement: A translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.

4 Organization and management

4.1 The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this Guide.

4.2 The laboratory shall

a) have managerial staff with the authority and resources needed to discharge their duties;

b) have arrangements to ensure that its personnel are free from any commercial, financial and other pressures which might adversely affect the quality of their work;

c) be organized in such a way that confidence in its independence of judgement and integrity is maintained at all times;

d) specify and document the responsibility, authority and interrelation of all personnel who manage, perform or verify work affecting the quality of calibrations and tests;

e) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel shall be such as to ensure adequate supervision;

f) have a technical manager (however named) who has overall responsibility for the technical operations;

g) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

h) nominate deputies in case of absence of the technical or quality manager;

i) where relevant, have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights;

j) where appropriate, participate in interlaboratory comparisons and proficiency testing programmes.

5 Quality system, audit and review

5.1 The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration and testing activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration or testing services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manager.

5.2 The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of this Guide. the quality manual and related quality documentation shall also contain

a) a quality policy statement, including objectives and commitments, by top management;

b) the organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts;

c) the relations between management, technical operations, support services and the quality system;

d) procedures for control and maintenance of documentation;

e) job descriptions of key staff and reference to the job descriptions of other staff;

f) identification of the laboratory's approved signatories (where this concept is appropriate);

g) the laboratory's procedures for achieving traceability of measurements;

h) the laboratory's scope of calibrations and/or tests;

i) arrangements for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

j) reference to the calibration, verification and/or test procedures used;

k) procedures for handling calibration and test items;

l) reference to the major equipment and reference measurement standards used;

m) reference to procedures for calibration, verification and maintenance of equipment;

n) reference to verification practices including interlaboratory comparisons, proficiency testing programmes, use of reference materials and internal quality control schemes;

o) procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;

p) the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications;

q) procedures for dealing with complaints;

r) procedures for protecting confidentiality and proprietary rights;

s) procedures for audit and review.

5.3 The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

5.4 The quality system adopted to satisfy the requirements of this Guide shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

5.5 All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timescale.

5.6 In addition to periodic audits the laboratory shall ensure the quality of results provided to clients by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

a) internal quality control schemes using whenever possible statistical techniques;

b) participation in proficiency testing or other inter-laboratory comparisons;

c) regular use of certified reference materials and/or in-house quality control using secondary reference materials;

d) replicate testings using the same or different methods;

e) re-testing of retained items;

f) correlation of results for different characteristics of an item.

6 Personnel

6.1 The testing laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

6.2 The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

6.3 Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory.

7 Accommodation and environment

7.1 Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

7.2 The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

7.3 The laboratory shall provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

7.4 There shall be effective separation between neighbouring areas when the activities therein are incompatible.

7.5 Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

7.6 Adequate measures shall be taken to ensure good housekeeping in the laboratory.

NOTE — It is the laboratory's responsibility to comply with the relevant health and safety requirements. This aspect, however, is outside the scope of this Guide.

8 Equipment and reference materials

8.1 The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this Guide are met.

8.2 All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

8.3 Each item of equipment including reference materials shall, when appropriate, be labelled, marked or otherwise identified to indicate its calibration status.

8.4 Records shall be maintained of each item of equipment and all reference materials significant to the calibrations or tests performed. The records shall include

a) the name of the item of equipment;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) date received and date placed in service;

d) current location, where appropriate;

e) condition when received (e.g. new, used, reconditioned);

f) copy of the manufacturer's instructions, where available;

g) dates and results of calibrations and/or verifications and date of next calibration and/or verification;

h) details of maintenance carried out to date and planned for the future;

i) history of any damage, malfunction, modification or repair.

9 Measurement traceability and calibration

9.1 All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established programme for the calibration and verification of its measuring and test equipment.

9.2 The overall programme of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall wherever applicable indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

9.3 Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable programme of interlaboratory comparisons or proficiency testing.

9.4 Reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards has not been invalidated.

9.5 Reference standards of measurement shall be calibrated by a body that can provide traceability to a national standard of measurement. There shall be a programme of calibration and verification for reference standards.

9.6 Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

9.7 Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

10 Calibration and test methods

10.1 The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

10.2 The laboratory shall use appropriate methods and procedures for all calibrations and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

10.3 Where methods are not specified, the laboratory shall, wherever possible, select methods that have been published in international or national standards, those published by reputable technical organizations or in relevant scientific texts or journals.

10.4 Where it is necessary to employ methods that have not been established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.

10.5 Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

10.6 Calculations and data transfers shall be subject to appropriate checks.

10.7 Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of calibration or test data, the laboratory shall ensure that:

a) the requirements of this Guide are complied with;

b) computer software is documented and adequate for use;

c) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

d) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data;

e) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

10.8 Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

11 Handling of calibration and test items

11.1 The laboratory shall have a documented system for uniquely identifying the items to be calibrated or tested, to ensure that there can be no confusion regarding the identity of such items at any time.

11.2 Upon receipt, the condition of the calibration or test item, including any abnormalities or departures from standard condition as prescribed in the relevant calibration or test method, shall be recorded. Where there is any doubt as to the item's suitability for calibration or test, where the item does not conform to the description provided, or where the calibration or test required is not fully specified, the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

11.3 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration or test item, during storage, handling, preparation, and calibration or test; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration or test item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

11.4 The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

12 Records

12.1 The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. It shall retain on record all original observations, calculations and derived data, calibration records and a copy of the calibration certificate, test certificate or test report for an appropriate period. The records for each calibration and test shall contain sufficient information to permit their repetition. The records shall include the identity of personnel involved in sampling, preparation, calibration or testing.

12.2 All records (including those listed in 8.4 pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client.

13 Certificates and reports

13.1 The results of each calibration, test, or series of calibrations or tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, in accordance with any instructions in the calibration or test methods. The results should normally be reported in a calibration certificate, test report or test certificate and should include all the information necessary for the interpretation of the calibration or test results and all information required by the method used.

13.2 Each certificate or report shall include at least the following information:

a) a title, e.g. "Calibration Certificate", "Test Report" or "Test Certificate";

b) name and address of laboratory, and location where the calibration or test was carried out if different from the address of the laboratory;

c) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

d) name and address of client, where appropriate;

e) description and unambiguous identification of the item calibrated or tested;

f) characterization and condition of the calibration or test item;

g) date of receipt of calibration or test item and date(s) of performance of calibration or test, where appropriate;

h) identification of the calibration or test method used, or unambiguous description of any non-standard method used;

i) reference to sampling procedure, where relevant;

j) any deviations from, additions to or exclusions from the calibration or test method, and any other information relevant to a specific calibration or test, such as environmental conditions;

k) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified;

l) a statement of the estimated uncertainty of the calibration or test result (where relevant);

m) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

n) where relevant, a statement to the effect that the results relate only to the items calibrated or tested;

o) a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.

13.3 Where the certificate or report contains results of calibrations or tests performed by sub-contractors, these results shall be clearly identified.

13.4 Particular care and attention shall be paid to the arrangement of the certificate or report, especially with regard to presentation of the calibration or test data and ease of assimilation by the reader. The format shall be carefully and specifically designed for each type of calibration or test carried out, but the headings shall be standardized as far as possible.

13.5 Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Certificate [or Test Report or Test Certificate], serial number... [or as otherwise identified]", or equivalent form of wording. Such amendments shall meet all the relevant requirements of clause 12 of this Guide.

13.6 The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.

13.7 The laboratory shall ensure that, where clients require transmission of calibration or test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of this Guide are met and that confidentiality is preserved.

14 Sub-contracting of calibration or testing

14.1 Where a laboratory sub-contracts any part of the calibration or testing, this work shall be placed with a laboratory complying with these requirements. The laboratory shall ensure and be able to demonstrate that its sub-contractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect of the work being sub-contracted. The laboratory shall advise the client in writing of its intention to sub-contract any portion of the testing to another party.

14.2 The laboratory shall record and retain details of its investigation of the competence and compliance of its sub-contractors and maintain a register of all sub-contracting.

15 Outside support services and supplies

15.1 Where the laboratory procures outside services and supplies, other than those referred to this Guide, in support of calibrations or tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations or tests.

15.2 Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

15.3 The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for calibrations or tests.

16 Complaints

16.1 The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

16.2 Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this Guide or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with 5.3 of this Guide.

International Organization for Standardization
Case postale 56 • CH-1211 GENEVA 20 • Switzerland

International Electrotechnical Commission
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Descriptors: laboratory accreditation, testing laboratories, tests, calibration, quality assurance.

Price based on 7 pages

GUIDE 43

First edition — 1984-10-01

Development and operation of laboratory proficiency testing

UDC 061.64

Ref. No. : ISO/IEC GUIDE 43-1984 (E)

Descriptors : certification, laboratories, efficiency.

Price based on 6 pages

Foreword

This document was drawn up by the ISO Committee on certification, ISO/CERTICO, in response to a request arising from the International laboratory accreditation conference (ILAC 82) held in Tokyo in October 1982. It was approved by the IEC Council in July 1984 and by the ISO Council in August 1984.

GUIDE 43-1984 (E)

Development and operation of laboratory proficiency testing

Preamble

Proficiency testing is the use of results generated in interlaboratory test comparisons for the purpose of assessing the technical competence of participating testing laboratories. Other purposes may be served by interlaboratory test comparisons, such as the determination of the precision of test methods described in ISO 5725, *Precision of test methods — Determination of repeatibility and reproducibility by inter-laboratory tests*, but these are outside the scope of this Guide.

Bodies assessing the technical competence of testing laboratories, such as accrediting bodies and certification bodies, use the results of proficiency testing in their assessment of technical competence to varying extents in their evaluation procedures depending on their particular policies. The Guide draws the important distinction between assessment of technical competence based solely on proficicency testing and assessment against pre-determined requirements such as those specified in ISO/IEC Guide 25, *General requirements for the technical competence of testing laboratories*, noting the limitations of assessments based on proficiency testing alone.

Attention is drawn to the need to distinguish between bodies assessing the technical competence of testing laboratories, which may organize and/or use proficiency testing among other assessment criteria and bodies which merely organize interlaboratory test comparisons. This Guide is directed towards the former, although factors to be taken into account in the organization of interlaboratory comparisons generally are indicated and a bibliography of some pertinent references is annexed to the Guide.

0 Introduction

0.1 Interlaboratory test comparisons on presumably "identical materials" do not, in general, yield identical results, due to many different factors referred to in ISO 5725.

0.2 The purposes for which interlaboratory test comparisons are undertaken may include

a) checking overall laboratory testing performance;

b) checking individual testing performance of laboratory staff;

c) establishing the effectiveness of a test method;

d) determining one or more characteristics of a material or product to a particular degree of accuracy.

Proficiency testing is the use of interlaboratory test comparisons for purpose (a) only.

0.3 Most bodies assessing the technical competence of testing laboratories require or expect satisfactory participation in proficiency testing as significant evidence of a testing laboratory's ability to produce reliable test results except where proficiency testing is inappropriate.

However, it is emphasised that a major distinction exists between :

a) the evaluation of the competence of a testing laboratory by the assessment of its total operation against pre-determined requirements, and

b) the examination of the results of a testing laboratory's participation in proficiency testing which may only be considered as

1 Scope and field of application

The object of this Guide is

a) to assist in the selection and organization of interlaboratory test comparisons for proficiency testing;

b) to describe the factors which should be taken into account in proficiency testing;

c) to describe how bodies assessing the technical competence of testing laboratories may use proficiency testing.

This Guide is intended for use by governmental or non-governmental bodies such as accrediting bodies and certification bodies, assessing the technical competence of testing laboratories. It may also be useful to assist testing laboratories in self-evaluation, but recognizes that proficiency testing is only one of a number of mechanisms which can contribute to the establishment of mutual confidence between different testing laboratories.

The Guide does not give operational details for interlaboratory test comparisons. A bibliography of some pertinent references is annexed to the Guide but is not exhaustive.

2 References

ISO 5725, *Precision of test methods — Determination of repeatability and reproducibility by inter-laboratory tests.*

ISO Guide 2, *General terms and their definitions concerning standardization, certification and testing laboratory accreditation.*

ISO/IEC Guide 25, *General requirements for the technical competence of testing laboratories.*

3 Definitions

The following definitions, taken from ISO Guide 2, are applicable :

3.1 testing laboratory : A laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of materials or products.

3.2 test method : A defined technical procedure to determine one or more specified characteristics of a material or product.

3.3 proficiency testing : Methods of checking laboratory testing performance by means of interlaboratory tests.

3.4 reference material (RM) : A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

In addition, the following definition applies for the purpose of the present Guide :

3.5 interlaboratory test comparisons : Organization, performance and evaluation of tests on the same or similar items or materials by two or more different laboratories in accordance with pre-determined conditions.

4 Proficiency testing and laboratory performance

4.1 Confidence that a testing laboratory consistently obtains reliable results is of the utmost importance to users of laboratory services. Users seeking such an assurance can undertake their own evaluation or can take note of the evaluation of other bodies.

4.2 The extent to which proficiency testing is used by bodies assessing the technical competence of testing laboratories and the use which is made of the information generated are matters of policy for the bodies themselves.

4.3 Where the outcome of the participation by a testing laboratory in proficiency testing may affect its status in relation to a body assessing the technical competence of testing laboratories, the body should provide documented procedures clearly defining beforehand its response to different possible outcomes.

4.4 Where appropriate, participation in proficiency testing may provide testing laboratories with information which may be useful in detecting possible sources of error where these exist.

5 Types of proficiency testing

5.1 Proficiency testing methods vary depending on the nature of the material or product under test, the test method in use and the number of testing laboratories participating. They possess the common feature of the comparison of test results obtained by one testing laboratory with those obtained by one or more other testing laboratories. In some cases, one of the participating laboratories may have a controlling function.

The following are types of proficiency testing programmes :

5.2 Type A

Where the item or material to be tested is circulated successively from one participating laboratory to the next.

The item or material may be returned to a central laboratory being used as a reference laboratory for the purpose of the proficiency test, for testing before being passed on to the next successive participating testing laboratory in order to determine whether any changes have taken place to the item or material.

Examples of items or materials used in this type of proficiency testing include audit devices, products, certified reference materials.

5.3 Type B

Where randomly selected sub-samples from a source of a suitable degree of homogeneity are distributed simultaneously to participating testing laboratories.

5.4 Type C

Where samples of a product or a material are divided into two or more parts with each participating laboratory testing one part of each sample. This is frequently referred to as "split sample" testing and differs from the type of proficiency testing described in 5.3, in particular when no control is possible over the homogeneity of the sample being divided.

6 Development of proficiency testing — General principles

6.1 The methods of operation within different organizations are not expected to be identical. Therefore, the contents of this clause are intended only as a guide to be modified appropriately to cater for particular situations.

6.2 Bodies assessing the technical competence of testing laboratories may organize proficiency testing programmes

a) as on-going interlaboratory test comparisons involving as many as possible of the test methods and all the laboratories for which they wish to use proficiency testing information; or

b) as particular interlaboratory test comparisons from time to time in response to particular perceived needs; or

c) on a basis intermediate between a) and b).

6.3 Bodies assessing the technical competence of testing laboratories may take advantage of suitable interlaboratory test comparisons organized by others, instead of or in addition to proficiency testing as described in 6.2.

In such cases, factors to be taken into consideration include :

a) the technical and statistical soundness of the test comparison;

b) access to the results;

c) participation by laboratories not currently involved in the interlaboratory test comparisons but which are subject to technical assessment by the body;

d) cost.

6.4 Bodies assessing the technical competence of testing laboratories which use proficiency testing should establish one or more specialist groups comprising persons with expertise in the test methods and interlaboratory testing to advise on general matters concerning proficiency testing and the interpretation of interlaboratory test comparisons.

6.5 The functions of the specialist group(s) may include :

a) providing advice to a body assessing the technical competence of testing laboratories on the use of proficiency testing as an element of its testing laboratory evaluation procedure, including the selection of types of proficiency testing to suit particular objectives;

b) the development and review of procedures for the planning, execution, analysis and reporting of interlaboratory test comparisons;

c) the identification and evaluation of interlaboratory test comparisons organized by other bodies with a view to their possible use by the body to which the specialist group reports;

d) the evaluation of proficiency test results as they may reflect the performance of participating laboratories.

6.6 The following matters should be taken into account by a body assessing the technical competence of testing laboratories in adopting proficiency testing as part of its assessment procedure :

a) the established policy of the body;

b) the feasibility of interlaboratory test comparisons in relation to the various tests for which the body undertakes an assessment of the technical competence of testing laboratories. Such factors as cost and the availability of suitable test item(s) and material(s) will be important;

c) the specific tests which may be most significant;

d) the measurement ranges which are to be examined;

e) the number of participating testing laboratories and the frequency of their participation;

f) whether participation by laboratories other than those being assessed is to be permitted;

g) the use of reference materials;

h) the establishment of criteria against which the performance of participating laboratories is to be assessed.

6.7 In general, the results generated in proficiency testing require statistical analysis which can be accomplished at different levels. The level of statistical analysis possible will depend on the design of the particular interlaboratory test comparison and should be taken into consideration at the design stage.

6.8 The level of understanding of statistical analysis among participating laboratories will vary. The results of proficiency testing, at least initially, should therefore be analyzed so as to show the results of each participating laboratory clearly in relation to those of the others. The use of histograms and charts may assist.

7 Interlaboratory test comparisons

7.1 The operation of particular interlaboratory test comparisons will require the guidance of persons with detailed technical knowledge and experience of the test methods involved. To this end the specialist group (see 6.4) may need to enlist one or more appropriate persons or may establish separate groups to supervise particular interlaboratory test comparisons.

7.2 Appropriate statistical design of an interlaboratory test comparison is essential and careful consideration should be given to the following matters and their interaction :

a) the inherent repeatability and reproducibility of the test(s) involved;

b) the smallest differences to be detected between participating laboratories at a desired confidence level;

c) the number of participating laboratories;

d) the number of samples to be tested and the number of repeat tests to be carried out on each sample.

In the absence of reliable information concerning a), it may be necessary to organize a pilot interlaboratory test comparison to obtain it.

7.3 Other matters which will need to be taken into account in the organization of an interlaboratory test comparison include the following :

a) the test method(s) to be used by participating laboratories;

b) the availability of suitable test samples and any conditions relating to the samples which may affect the integrity of the test comparison such as homogeneity, shelf life, possible damage in transit and effects of ambient conditions;

c) the provision of detailed instructions covering all aspects of the interlaboratory test comparison which must be adhered to by the participating laboratories including details of the procedure to be followed in reporting results to the organizing body;

d) the preservation of anonymity amongst participating laboratories.

Bibliography of some pertinent references which may assist bodies in the establishment and operation of proficiency testing

[1] YOUDEN, W.J., Graphical Diagnosis of Interlaboratory Test Results, *Industrial Quality Control IX*, II, May 1959, pp. 1-5 (reprinted in *Precision Measurement and Calibration. Statistical concepts and Procedures*, H. H. Ku, Ed., Special Publication 300 National Bureau of Standards, Washington D.C., Vol. 1, Feb. 1969).

[2] MANDEL, J. and LASHOF, T.W., The Interlaboratory Evaluation of Testing Methods, *ASTM Bulletin No. 239*, July 1959, pp. 53-61.

[3] Manual for Conducting an Interlaboratory Study of a Test Method, *Special Technical Publication 335*, American Society for Testing and Materials, Philadelphia, 1963.

[4] YOUDEN, W.J. and STEINER, E.H., *Statistical Manual of the Association of Official Analytical Chemists*, Association of Official Analytical Chemists, Washington, Jan. 1975.

[5] BS 5233, *Glossary of terms used in metrology*, British Standards Institution, London, 1975.

[6] MANDEL, J., The Analysis of Interlaboratory Test Data, *ASTM Standardization News 5*, 3 March 1977, pp. 17-20, 56.

[7] *Interlaboratory Testing Techniques*, Chemical Division, American Society for Quality Control, Milwaukee, Wisconsin, 1978.

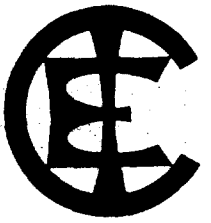
[8] LASHOF, T.W., The Measuring Process and Laboratory Evaluation, *National Bureau of Standards Special Publication* 591 : Proceedings of the National Conference on Testing Laboratory Performance; Evaluation and Accreditation, held at NBS, Gaithersburg, M.D., Sept. 25-26, 1979; NBS, Washington, August 1980, pp. 25-30.

[9] *Standard Practice for Conducting an Interlaboratory Test Program to Determine the Precision of Test Methods*, ASTM E 691-79, 1980 Annual Book of ASTM Standards, Part 41, American Society for Testing and Materials, Philadelphia.

See also ASTM Standards relating to Interlaboratory Test Programmes for specific materials and products.

[10] *Evaluation and Accreditation of Inspection and Test Activities*, Harvey Schock, Ed., ASTM STP 814, Philadelphia, August 1983.

NOTE — Information on existing national standards related to the above subject may be obtained from the relevant ISO member bodies or IEC national committees.



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GUIDE 58

Calibration and testing laboratory accreditation systems — General requirements for operation and recognition

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Contents

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) together form a system for worldwide standardization as a whole. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

This Guide replaces ISO/IEC Guide 54:1988, *Testing laboratory accreditation systems — General recommendations for the acceptance of accreditation bodies*, and ISO/IEC Guide 55:1988, *Testing laboratory accreditation systems — General recommendations for operation*. It was drawn up by the ISO Council Committee on conformity assessment, ISO/CASCO, on the basis of a draft transmitted by the International Laboratory Accreditation Conference (ILAC '90) and in collaboration with laboratory experts.

Its object is to provide guidance for the setting up and operation of a laboratory accreditation body and to facilitate agreements between such bodies on mutual recognition of accreditation of testing laboratories.

Whilst ISO/IEC Guides such as this are intended to provide guidance, it is hoped that any changes from the documents made in introducing systems nationally would be minimal. In recognition of the fact that some countries may choose to adopt the Guides directly, they are written to enable this to be done by including words such as "shall" to indicate those aspects which desirably would be mandatory. The overriding basis that the document is intended to provide guidance holds good.

It is only in recent years that national accreditation bodies have developed on a large scale because of the necessity to make available testing services of an assessed level of quality to all sectors of the economy and also to facilitate mutual acceptance of calibration and test results.

This Guide was approved by the ISO Council Committee on conformity assessment (ISO/CASCO) in September 1992 and by the IEC Council in October 1992.

Calibration and testing laboratory accreditation systems — General requirements for operation and recognition

1 Scope

This document sets out the general requirements for the operation of a system for accreditation of calibration and/or testing laboratories so that the accreditations granted and the services covered by the accreditations may be recognized at a national or an international level and the body operating the accreditation system may be recognized at national or international level as competent and reliable.

Users of the services of an accreditation body, other than the laboratories accredited by that accreditation body, may require compliance with requirements additional to those specified in this document.

The object of this document is to provide guidance for the setting up and operation of an accreditation body and to facilitate agreements on mutual recognition of accreditation of laboratories between such bodies.

NOTE – It is recognized that agreements on mutual recognition of accreditations aiming at the removal of barriers to across-border trade may have to cover other aspects not explicitly specified in these general requirements, such as proficiency testing or other interlaboratory comparisons, exchange of staff or training programmes. In particular, with a view to creating confidence and harmonizing the interpretation and implementation of standards, each accreditation body should encourage technical cooperation and exchange of experience among laboratories accredited by it, and it should be prepared to exchange information on accreditation procedures and practices with other accreditation bodies.

2 References

ISO/IEC Guide 2:1991, *General terms and their definitions concerning standardization and related activities.*

ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories.*

ISO/IEC Guide 43:1984, *Development and operation of laboratory proficiency testing.*

ISO 8402, *Quality management and quality assurance — Vocabulary.*

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing.*

ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors.*

3 Definitions

The relevant definitions contained in ISO/IEC Guide 2 are applicable.

In addition, the following definitions apply for the purposes of this document:

3.1 laboratory: Body that calibrates and/or tests.

[3.1 of ISO/IEC Guide 25:1990]

3.2 accreditation: Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

NOTE – Accreditation does not of itself qualify the laboratory to approve any particular product. However, accreditation may be relevant to approval and certification authorities when they decide whether or not to accept data produced by a given laboratory in connection with their own activities.

[13.7 of ISO/IEC Guide 2:1991, with the addition of a note]

For the purposes of this document the term "client" refers to any organization or person that engages the services of a calibration or testing laboratory.

4 Accreditation body

4.1 General provisions

4.1.1 The procedures under which the accreditation body operates shall be administered in a non-discriminatory manner.

Access to an accreditation system operated by an accreditation body shall not be conditional upon the size of the laboratory or membership of any association or group, nor shall there be undue financial conditions to restrict participation.

4.1.2 The competence of an applicant laboratory shall be assessed by the accreditation body against all of the requirements of ISO/IEC Guide 25.

4.1.3 The requirements of ISO/IEC Guide 25 may have to be interpreted for a specific calibration, test, or type of calibration or test by the accreditation body. These interpretations shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence. They shall be published by the accreditation body.

4.1.4 The accreditation body shall require accredited laboratories to maintain impartiality and integrity.

4.1.5 The accreditation body shall confine its requirements, assessment and decision on accreditation to those matters specifically related to the scope of the accreditation being considered.

4.2 Organization of the accreditation body

4.2.1 The accreditation body shall

a) be a legally identifiable, public or private entity;

b) have rights and responsibilities relevant to its accreditation activities;

c) have adequate arrangements to cover liabilities arising from its operations and/or activities;

d) have the financial stability and resources required for the operation of an accreditation system;

e) have and make available on request a description of the means by which it receives its financial support;

f) employ a sufficient number of personnel having the necessary education, training, technical knowledge and experience for handling the type, range and volume of work performed, under a senior executive who is responsible to the organization, body or board to which it reports;

g) have a quality system, including an organizational structure, that enables it to give confidence in its ability to operate a laboratory accreditation system satisfactorily;

h) have documented policies and procedures for the operation of the quality system that include

— policies and decision-making procedures that distinguish between laboratory accreditation and any other activities in which the body is engaged;

— policies and procedures for the resolution of complaints and appeals received from laboratories about the handling of accreditation matters, or from users of services about accredited laboratories or any other matters;

i) together with its senior executive, and staff, be free from any commercial, financial and other pressures which might influence the results of the accreditation process;

j) have formal rules and structures for the appointment and operation of committees involved in the accreditation process; such committees shall be free from any commercial, financial and other pressures that might influence decisions or shall have a structure where members are chosen to provide impartiality through a balance of interests where no single interest predominates;

k) establish one or more technical committees, each responsible, within its scope, for advising the accreditation body on the technical matters relating to the operation of its accreditation system;

l) not offer consultancies or other services which may compromise the objectivity of its accreditation process and decisions;

m) have arrangements that are consistent with applicable laws, to safeguard, at all levels of its organization (including committees), confidentiality of the information obtained relating to applications, assessment and accreditation of laboratories.

4.2.2 The accreditation body shall have arrangements for either controlling the ownership, use and display of the accreditation documents or controlling the manner in which an accredited laboratory may refer to its accredited status, or both.

4.3 Quality system

4.3.1 The accreditation body shall operate a quality system appropriate to the type, range and volume of work performed. This system shall be documented and the documentation shall be available for use by the accreditation body staff. The accreditation body shall designate a person having direct access to its highest executive level, to take responsibility for the quality system and the maintenance of the quality documentation.

4.3.2 The quality system shall be documented in a quality manual and associated quality procedures, and the quality manual shall contain or refer to at least the following:

a) a quality policy statement;

b) the organizational structure of the accreditation body;

c) the operational and functional duties and services pertaining to quality, so that each person concerned will know the extent and the limits of their responsibility;

d) administrative procedures including document control;

e) policies and procedures to implement the accreditation process;

f) arrangements for feedback and corrective actions whenever discrepancies are detected;

g) the policy and procedures for dealing with appeals, complaints and disputes;

h) the policy and procedures for conducting internal audits;

i) the policy and the procedures for conducting quality system reviews;

j) the policy and the procedures for the recruitment and training of assessors and monitoring their performance.

4.3.3 The accreditation body shall audit its activities to verify that they comply with the requirements of the quality system. The quality system shall also be reviewed to ensure its continued effectiveness. Audits and reviews shall be carried out systematically and periodically and recorded together with details of any corrective actions taken.

4.3.4 The accreditation body shall maintain records to demonstrate that accreditation procedures have been ef-